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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,940	01/31/2001	Stanley L. Mills	5157.002	6337

30589 7590 03/11/2004

DUNLAP, CODDING & ROGERS P.C.
PO BOX 16370
OKLAHOMA CITY, OK 73113

EXAMINER

MONDESI, ROBERT B

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

9-27-1

Office Action Summary

Application No.

09/774,940

Applicant(s)

MILLS ET AL.

Examiner

Robert B Mondesi

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6,7,21 and 25-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,7,21 and 25-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Applicant's election of Invention of Group I, **Claims 1-2, 6-7 and 21, 25-29**, in amendment filed December 17, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore the requirement is still deemed proper and is made FINAL. **Claims 3-5, 8-20, 22-24** are cancelled by the applicant. **Claims 1-2, 6-7 and 21, 25-29** are pending in this application.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading "This is a continuation of Application No. 09/021,085, filed February 10, 1998 now abandoned." should be entered following the

title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

Preliminary Amendment

The preliminary amendment filed May 05, 2001 has been entered.

Information Disclosure Statement

The IDS filed May 17, 2001 has been received and is signed and considered, a copy of the IDS is attached to the following document.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 6-7 21 and 25-29 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **Claims 1-2, 6-7 21 and 25-29** cite a general compound formula for zinc finger peptides, that can form a complex by chelation with a metal atom in order to form a zinc finger analogue. Examples 1-2 discuss a method for the formation of a chelated zinc finger peptide analogue comprising a peptide designated by SEQ ID NO: 1. However, the specification does not provide a written description in regards the synthesis of the multitude of

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compounds/peptides provided for by general peptide formula in **claims 1-2, 6-7, 21 and 24-29** or the zinc finger peptide designated by SEQ ID NO: 1. This information is presently lacking in regards to the zinc finger peptides proposed by the general formula of **claims 1-2, 6-7, 21 and 24-29**, for a variety of reasons. In order to manufacture a peptide a person skill in the art needs to know the sequence of the peptide, the general formula of **claims 1-2, 6-7, 21 and 24-29** does not provide such information. The specification provides only the sequence for one zinc finger peptide and that is the peptide designated by SEQ ID NO:1. It is not possible for a person skill in the art to manufacture a peptide without knowing its amino acid sequence, furthermore a person skill in the art may be inclined to manufacture a given peptide, such as the peptide designated by SEQ ID NO:1, using a variety of methods. These methods can include the use of a peptide synthesizer or recombinant technology. However a person skill in the art will not know the best mode for the manufacture of the specific zinc finger peptide designated by SEQ ID NO:1, because the applicant has not provided a written description for manufacturing the mentioned peptide. In example 2 (page 2), the specification states that, the zinc finger peptide designated by SEQ ID NO: 1 was made (without mentioning a specific method of synthesis, i.e., recombinant vs. peptide synthesizer) and radiolabeled. A written description of the claimed subject matter, chealted zinc finger peptide analogues, needs to include instructions that enable a person skill in the art as to how to make and use the invention in view of the best mode contemplated by the inventor. In regards to the possible zinc finger peptides proposed by the general formula of **claims 1-2, 6-7, 21 and 24-29** and the zinc finger peptide

designated as SEQ ID NO: 1, the specification does not provide a written description to a person skill in the art the manner and process of making and using the invention in accordance with the best mode contemplated by the inventor.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 6-7 21 and 25-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In **claims 1-2, 6-7, 21 and 25-29** the variable "n" that is part of the general formula presented in the claims, has not been defined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 6-7 and 21, 25-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Bray et al. Bray et al. disclose a peptide with zinc finger motif that is capable of binding ligands such as metals (page 9563, column 1, lines 1-45). The primary structure of this peptide is in accordance to the requirements of the general formula presented in **claims 1-2, 6-7 and 21, 25-29**. Residue 10 is a cysteine (X₁), residue 13 is also a cysteine in (X₂), residue 26 is a histidine (X₃), residue 30 is a

histidine (X₄) (NCBI, AAA61329) (**present claims 1-2, 6-7 and 21, 25-29**). Thus Bray et al. teach all the elements of **claims 1-2, 6-7 and 21, 25-29** and these claims are anticipated under 35 USC 102(b).

Claims 1-2, 6-7 and 21, 25-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Michael et al. . Michael et al. et al disclose a peptide with zinc finger motif that is capable of binding metals such as Cobalt (page 4796-4800). The primary structure of this peptide is in accordance to the requirements of the general formula presented in **claims 1-2, 6-7 and 21, 25-29**. Residue 4 is a cysteine (X₁), residue 7 is also a cysteine in (X₂), residue 20 is a histidine (X₃), residue 24 is a histidine (X₄) (page 4796, line 2) (**present claims 1-2, 6-7 and 21, 25-29**). Thus Michael et al. teach all the elements of **claims 1-2, 6-7 and 21, 25-29** and these claims are anticipated under 35 USC 102(b).

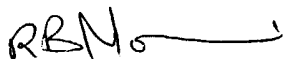
Conclusion

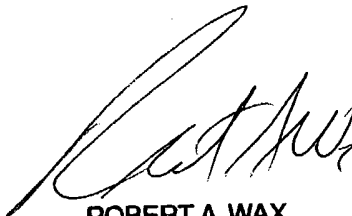
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Robert B Mondesi
Patent Examiner
Group 1653
03-05-04


ROBERT A. WAX
PRIMARY EXAMINER